
CALIFORNIA STEM CELL BOARD APPROVES TERMS FOR GRANTS TO FOR-PROFIT RESEARCH ENTITIES Scientific Strategic Plan Adopted CIRM President Announces Retirement

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IRVINE, CA, December 7, 2006 – The Independent Citizens Oversight Committee (ICOC), governing board of the California Institute for Regenerative Medicine (CIRM), today approved terms and conditions for grants to for-profit entities engaged in stem cell research. The unanimous decision came at the ICOC's meeting at the University of California, Irvine.

The groundbreaking policy was developed by the ICOC Intellectual Property Task Force, and follows a similar policy for non-profit institutes adopted in February. It guarantees that the State of California will realize a tiered-return on CIRM stem cell research grants to for-profit entities whenever a commercial, CIRM-funded project generates \$500,000 in revenue. The state's financial participation will rise with a project's success, and will include royalty payments for any initiative that achieves "blockbuster" status of \$500 million in annual revenue. No other California or federal agency funding biomedical research sets similar terms and conditions for grants.

"We have again adopted cutting edge policies for cutting edge science," said Robert N. Klein, chair of the ICOC. "Today's action affirms our commitment to standards and regulations that are the 'gold standard' for publicly funded stem cell research."

In addition to financial returns, CIRM expects the state to benefit from its investments by requiring for-profit grant recipients to make stem cell therapies accessible to California residents. The policy requires for-profit entities to file plans making CIRM-funded therapies available to uninsured Californians that are consistent with industry standards; to provide discounted prices to publicly-funded health care plans; and to give preference to California residents if therapies are in short supply.

"Californians are paying for this research," said Klein. "Californians should expect a reasonable share of its financial and medical benefits."

Approval of the policy allows the CIRM to consider grant applications from for-profit research organizations in California while final regulations are in progress. Draft regulations based on the new policy will be submitted to the state Office of Administrative Law for additional public review and comment, and are expected to be final in 2007.

The ICOC also gave final approval to the CIRM Scientific Strategic Plan, which identifies 25 initiatives that will guide the Institute's funding decisions for 10 years, for the \$3 billion in bond funds voters approved in 2004. CIRM has incorporated a "1000 Days" plan, outlining a schedule of grants to be awarded in the next three years to jump start stem cell research in California. The plan includes measurable goals that will be used to monitor CIRM's progress and adjust its priorities over the coming decade. CIRM expects to have preliminary evidence of clinical efficacy (clinical proof of principle) for at least one therapy based on embryonic stem cells for one disease by the tenth year, with additional stem cell therapies for as many as four diseases in early stage clinical trials. In addition, the research should substantially advance the understanding of chronic disease, as well as the development of diagnostic tools to enhance, test, and validate stem cell therapies. The plan has been in development since last October, and has involved consultations with more than 200 scientific experts and patient advocates.

"Ours is a bold scientific venture, directed at a very young field," said Zach W. Hall, Ph.D., CIRM's President and Chief Scientific Officer. "Human embryonic stem cells were first isolated in 1998. There is much we do not yet know about why and how they differentiate into other types of cells, how we might direct them down specific paths, and how to control their development. What we do know is that embryonic stem cells have enormous potential. The challenge is to harness their power. Our strategic plan moves that research far down the field."

The ICOC also adopted a number of revisions to the Institute's travel and contracting policies. The changes were prompted in the course of a review of CIRM's policies, procedures, and practices by the California Bureau of State Audits (BSA), requested by the state legislature earlier this year. "We have identified several ways in which we can improve our operations," said Hall. "Rather than wait for the BSA's final report, which is expected in March, we wish to strengthen these policies now. We are happy to do so at this time in preparation for availability of full public bond funding." Hall said he expects additional policy modifications in the coming months.

This past week, CIRM conducted a review of its first research grant applications. Its Grants Working Group – composed of 15 scientific experts and 32 specialists from outside the state, along with the ICOC's eight patient advocate members – spent three days reviewing 232 applications for 30 grants totaling \$24 million. Hall reported that the session had gone well, and that the panel's recommendations would be presented to the ICOC in February. Dr. Dennis Steindler, executive director of the McKnight Brain Institute at the University of Florida and a member of the CIRM Grants Working Group, said, "We were all impressed by the quality of the scientific projects and by how well CIRM organized the review process. Every funding agency should be run as well. California is fortunate to have so many talented stem cell researchers and dedicated CIRM administrators working in the field."

Hall informed the ICOC that he intends to retire sometime in the next six months, with a specific date to be determined. "This is a wonderful project," he said. "It has been a privilege to lead the Institute in its early, formative years, and I am grateful to the ICOC for giving me the opportunity to do so. I am proud of what we have accomplished so far and look forward to the next six months as we fund the first CIRM grants for human embryonic stem cell research in California."

About CIRM

Governed by the ICOC, CIRM was established in 2004 with the passage of Proposition 71, the California Stem Cell Research and Cures Initiative. The statewide ballot measure, which provided \$3 billion in funding for stem cell research at California universities and research institutions, was approved by California voters, and called for the establishment of an entity to make grants and provide loans for stem cell research, research facilities, and other vital research opportunities. For more information, please visit www.cirm.ca.gov.

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